STANDARD OPERATING PROCEDURE TEMPLATE · PRE-ANALYTIC: ORDERING, COLLECTION AND SPECIMEN HANDLING

Venipuncture (Routine Blood Collection)

Governing requirement: 42 CFR 493.1242(a)

Applies to: ☑ Waived ☑ Moderate complexity ☑ High complexity

Laboratory name		**CLIA number**	
Document number		**Version**	
Effective date		**Next review due**	
Author		**Department / section**	
Approved by (laboratory director)		**Director signature**	
Approval date		**Supersedes document**	

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1. Purpose

To collect venous blood specimens safely and in a way that preserves specimen integrity.

2. Scope

Routine venipuncture by evacuated tube, syringe or butterfly on adults and children **[Age limits]**.

Age limits

3. Responsibility

- Collectors (phlebotomists, nurses, medical assistants): follow this procedure and document collection.
- Specimen processing / accessioning staff: check acceptability and document problems.
- Supervisor: trains staff, monitors pre-analytic errors and reviews rejection logs.
- Laboratory director: approves the procedure and acceptance criteria.

4. Definitions

Order of draw: The sequence used to avoid additive carryover: blood culture or sterile tubes; sodium citrate; serum tubes with or without clot activator or gel; heparin; EDTA; sodium fluoride/potassium oxalate.

5. Materials, equipment and records

- Gloves, tourniquet, 70% isopropyl alcohol pads
- Safety needles and holders **[Needle gauges stocked]**

Needle gauges stocked

- Tubes per test menu
- Gauze, bandages, sharps container

6. Procedure

1. Perform hand hygiene and put on gloves.

2. Identify the patient with two identifiers and check fasting or timing requirements.

3. Position the patient seated or lying down; never standing.

4. Apply the tourniquet 3-4 inches above the site for no more than 1 minute.

5. Select a vein, preferably the median cubital; avoid arms with IVs, fistulas or on the side of mastectomy unless approved.

6. Clean the site with alcohol and let it air dry.

7. Anchor the vein and insert the needle bevel up at about 15-30 degrees.

8. Fill tubes in order of draw; let vacuum tubes fill completely.

9. Release the tourniquet as blood flow begins or within 1 minute.

10. Invert tubes gently per the tube manufacturer **[Inversions per tube type]**.

Inversions per tube type	

11. Withdraw the needle, activate the safety device immediately and discard in the sharps container.

12. Apply pressure; check bleeding has stopped before bandaging.

13. Label tubes at the bedside with two identifiers, date/time and collector initials.

14. Document collection; transport per the transport SOP.

7. Quality control

• Monitor hemolysis rate and recollection rate by collector.

8. Interpretation, reporting and documentation

• Document unsuccessful attempts and patient reactions.

9. Limitations and cautions

• Limit attempts to **[Maximum attempts]** per collector.

Maximum attempts	

• This is a generic template. Adapt it to your instruments, test systems, manufacturer instructions, state law and accreditation standards before use.

10. References

• eCFR, 42 CFR Part 493 Laboratory Requirements (CLIA)
https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493

• CMS, State Operations Manual Appendix C: Survey procedures and interpretive guidelines for laboratories
https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107ap_c_lab.pdf

• OSHA, 29 CFR 1910.1030 Bloodborne pathogens
https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030

• CLSI guidelines relevant to this procedure (referenced by name only; obtain current editions from CLSI)

• eCFR, 42 CFR 493.1242 https://www.ecfr.gov/current/title-42/section-493.1242

11. Lab-specific notes

Notes and local requirements	

12. Revision history

Version	Date	Description of change	Author	Approved by

13. Annual review log

Procedures and changes must be approved, signed and dated by the current laboratory director before use (42 CFR 493.1251(d)).

Review date	Reviewed by	Signature	Changes needed (Y/N)	Comments

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